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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,039	08/06/2002	Bonnie Davis	U 013729-7	8014
<div>140 7590 11/02/2007</div> <div>LADAS & PARRY</div> <div>26 WEST 61ST STREET</div> <div>NEW YORK, NY 10023</div>				
			<div>EXAMINER</div> <div>WILLIAMS, LEONARD M</div>	
			<div>ART UNIT</div> <div>1617</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>11/02/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/980,039

Applicant(s)

DAVIS, BONNIE

Examiner

Leonard M. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 12-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/02, 11/27/01</u> . | 6) <input type="checkbox"/> Other: ____ |

Detailed Action

Response to Amendment

The amendment received 08/06/2007 amending claim 1 and canceling claims 3 and 11 is entered. The amendment of claim 1 is to incorporate the language and substance of claims 3 and 11. Claims 1-2 and 12-22 are currently pending.

The amendment of claim 1 is sufficient to overcome the 112-1st rejection of the last office action.

Response to Arguments

Applicant's arguments filed 08/06/2007 have been fully considered but they are not persuasive. The applicant's have argued that the Saito reference while stating that "augmented cholinergic processes apparently stimulate the release of egg from the follicle" it does not provide motivation for the use of acetylcholinesterase inhibitors to induce ovulation in humans as Saito only demonstrates this activity in rabbits. The examiner respectfully points out that the applicant's have apparently provided only prophetic examples for the treatment of humans (along with some references to demonstrate how they would perform the testing). Further the applicant's state on page 8 that "Cholinergic agents stimulate gonadotropin secretion in short-term studies of experimental animals and are of use in promoting the development of additional follicles during normal menstrual cycles in infertility cases". This clearly indicates that some

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animals can be utilized to test the infertility reversing effects of cholinergic agents. The applicant's stance that the use of rabbits is not appropriate in the prior art for obviating the use in humans does not hold as stated. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

For the reasons stated above and for the reasons of record the 103(a) rejection is maintained. The 103(a) rejection as written obviates the claims as amended and thus does not need to be modified except to include the cancellation of claims 3 and 11.

The rejection is reproduced below.

The 112-1st rejection has been withdrawn.

This action is made **final**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walles et al. (*European Journal of Obstetrics and Gynecology and Reproductive Biology*, 4 (1S), s103-s107) in view of each of Yorke et al. (*Biology of Reproduction*,

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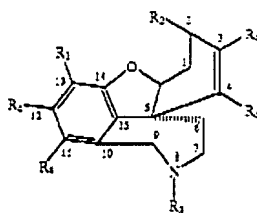
22(4), 897-912), Trubnikova et al. (*Ontogenez*, 20(5), 532-542, relying on English abstract), and Davis et al. (USPN 6150354).

Walles et al. teaches that acetylcholine causes contraction in human and cow follicles (p s107). Walles does not specifically teach the administration of an acetylcholinesterase inhibitor or that contraction of follicles induces ovulation.

Yorke et al. teaches that muscular contraction is associated with the expulsion of the egg from the follicle in vertebrates.

Trubnikova et al. teaches that contraction of follicular epithelium cells resulted in the retraction of the egg envelopes.

Davis et al. teaches that acetylcholinesterase inhibitors of the following formula:



wherein R₁ may be a monoalkyl or dialkyl carbamate, etc. It is also noted that galanthamine, and specific alkyl carbamates are taught as acetyl cholinesterase inhibitors (col. 29, line 35-col.30, line 60). Davis et al. also teaches that it is possible to increase acetylcholine levels by decreasing the amount or activity of the acetylcholinesterase (col. 7, lines 44-48).

It would have been obvious to one of ordinary skill in the art to administer an acetylcholinesterase inhibitor of Davis et al. in order to induce ovulation because (1) Davis et al. teaches that the inhibition of acetylcholinesterase causes an increase in

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acetylcholine; (2) Walles et al. teaches that acetylcholine causes the the follicles to contract; and (3) both Yorke et al. and Trubnikova teach that the contraction of follicles is associated with the release of the egg (ovulation). One would have been motivated to administer the acetylcholinesterase inhibitors of Davis et al. because of an expectation of success in inducing release of the egg from the follicle.

It is noted that the claimed recitation of a central effect and a duration of action of from 1 to 100 hours is a property of the acetylcholinesterase to be administered. Since the same compounds are cited herein as obvious, the limitation is met. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

It is further noted that the combined references have rendered obvious a treatment for the induction of ovulation. Accordingly, the combined references render obvious a treatment of a condition which can benefit from the stimulation of the hypothalamic-pituitary-gonad axis (failure to ovulate).

Claim Rejections - 35 USC § 103

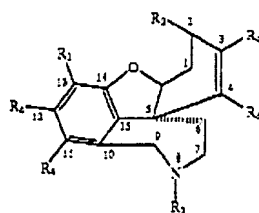
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 12-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Saiko et al. (82CA:96010) in view of Davis et al. (USPN 6150354).

Saiko et al. teaches that augmented cholinergic processes stimulate the release of the egg from the follicle.

Davis et al. teaches that acetylcholinesterase inhibitors of the following formula:



wherein R₁ may be a monoalkyl or dialkyl carbamate, etc. It is also noted that galanthamine, and specific alkyl carbamates are taught as acetyl cholinesterase inhibitors (col. 29, line 35-col.30, line 60). Davis et al. also teaches that it is possible to increase acetylcholine levels by decreasing the amount or activity of the acetylcholinesterase (col. 7, lines 44-48).

It would have been obvious to one of ordinary skill in the art to administer an acetylcholinesterase inhibitor of Davis et al. in order to induce ovulation because (1) Davis et al. teaches that the inhibition of acetylcholinesterase causes an increase in acetylcholine; and (2) Saiko et al. teaches that cholinergic activity stimulates the release of the egg from the follicle (ovulation). One would have been motivated to administer the acetylcholinesterase inhibitors of Davis et al. because of an expectation of success in inducing release of the egg from the follicle (inducing ovulation).

It is noted that the claimed recitation of a central effect and a duration of action of from 1 to 100 hours is a property of the acetylcholinesterase to be administered. Since the same compounds are cited herein as obvious, the limitation is met. A compound

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and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

It is further noted that the combined references have rendered obvious a treatment for the induction of ovulation. Accordingly, the combined references render obvious a treatment of a condition which can benefit from the stimulation of the hypothalamic-pituitary-gonad axis (failure to ovulate).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER